510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
k040455

B. Analyte:
Uric Acid

C. Type of Test:
Quality control material for quantitative uric acid assay

D. Applicant:
Cliniqa, Inc.

E. Proprietary and Established Names:
LiniCAL™ Uric Acid Calibration Verifiers

F. Regulatory Information:

1. Regulation section:
   21 CFR § 862.1660, Quality control material (assayed and unassayed)
2. Classification:
   Class I
3. Product Code:
   JJX, Single (specified) analyte controls (assayed and unassayed)
4. Panel:
   Clinical Chemistry (75)

G. Intended Use:

1. Indication(s) for use:

Cliniqa LiniCAL™ Calibration Verifiers Levels A-E for Olympus AU Systems are assayed, liquid, quality control products which may be used to evaluate the performance of the Olympus AU Systems for Uric Acid at five useful concentrations.

2. Special condition for use statement(s):

For professional prescription use only

3. Special instrument Requirements:

Olympus AU Systems

H. Device Description:

The LiniCAL Uric Acid Calibration Verifiers are human serum-based, containing constituents of human origin. They are used in the clinical laboratory to verify calibration and/or assess linearity of the Olympus AU Systems. Five assayed levels of uric acid are provided to allow monitoring of the reportable range.

I. Substantial Equivalence Information:

1. Predicate device name(s):
   Cliniqa LiniCAL Chemistry Calibration Verifiers, Levels A-E for Beckman Synchron Systems
2. Predicate K number(s):
   k031921
3. Comparison with predicate:

Both devices are human serum-based products that are manufactured using the same processes. They differ in that the constituents in the predicate device are albumin, BUN, calcium, creatinine, lactate, magnesium, phosphorus, total protein, triglycerides, glucose, iron, sodium, potassium, and chloride, and the constituent in the subject device is uric acid.

J. Standard/Guidance Document Referenced (if applicable):

None referenced.

K. Test Principle:

Not applicable. This submission is for assayed control material.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. *Precision/Reproducibility:*
      Not applicable. This submission is for assayed control material.
   b. *Linearity/assay reportable range:*
      Not applicable. This submission is for assayed control material.
   c. *Traceability (controls, calibrators, or method):*

The five levels of controls are prepared gravimetrically in a human serum-based matrix. The values are assigned using a commercially available assay. The targeted values of the five levels of controls are 3 +/- 0.300, 9.75 +/- 1.95, 16.5 +/- 3.30, 23.3 +/- 4.65, and 30.0 +/- 3.00 mg/dL.

Stability studies are described for real-time, open vial, and accelerated stability evaluation. Acceptance criteria are defined as +/- 10 % of the reference value.

   d. *Detection limit:*
      Not applicable. This submission is for assayed control material.
   e. *Analytical specificity:*
      Not applicable. This submission is for assayed control material.

f. Assay cut-off:
Not applicable. This submission is for assayed control material.

2. Comparison studies:
   a. Method comparison with predicate device:
   Not applicable. This submission is for assayed control material.
   b. Matrix comparison:
   Not applicable. This submission is for assayed control material.

3. Clinical studies:
   a. Clinical sensitivity:
   Not applicable. This submission is for assayed control material.
   b. Clinical specificity:
   Not applicable. This submission is for assayed control material.
   c. Other clinical supportive data (when a and b are not applicable):
   Not applicable. This submission is for assayed control material.
4. Clinical cut-off:
   Not applicable. This submission is for assayed control material.
5. Expected values/Reference range:
   Not applicable. This submission is for assayed control material.

M. Conclusion:

I recommend that the LiniCAL™ Uric Acid Calibration Verifiers are substantially equivalent to the legally marketed predicate device.